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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/602,242

06/24/2003

Ye Fang

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CORNING INCORPORATED  
SP-TI-3-1  
CORNING, NY 14831

EXAMINER

YANG, NELSON C

ART UNIT

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PAPER

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

<b>Office Action Summary</b>	<b>Application No.</b> 10/602,242	<b>Applicant(s)</b> FANG ET AL.	
	<b>Examiner</b> Nelson Yang	<b>Art Unit</b> 1641	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☒ Responsive to communication(s) filed on 31 March 2008.
- 2a) ☐ This action is **FINAL**.                      2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☒ Claim(s) 1-18, 27 and 42-61 is/are pending in the application.
- 4a) Of the above claim(s) 3, 6-8 and 27 is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1, 2, 4, 5, 9-18 and 42-61 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 24 June 2003 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All    b) ☐ Some \*    c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

### Attachment(s)

- |                                                                                      |                                                                   |
|--------------------------------------------------------------------------------------|-------------------------------------------------------------------|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)          | 4) <input type="checkbox"/> Interview Summary (PTO-413)           |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____                                      |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)          | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date _____                                                          | 6) <input type="checkbox"/> Other: _____                          |

## **DETAILED ACTION**

### ***Response to Amendment***

1. Claims 1, 2, 4, 5, 9-18, 42-61 are currently under examination.
2. Claims 3, 6-8, 27 are withdrawn.

### ***Rejections Withdrawn***

3. Applicant's arguments, see p.9-12, filed March 31, 2008, with respect to the rejection of claims 1, 2, 4-5, 9-16, 18, 42-50, 52, 54, 56, 58, 59, under 35 U.S.C. 103(a) as being unpatentable over Yamazaki et al. [US 6,699,719] in view of Umek et al. [US 2003/0124572] have been fully considered and are persuasive. The rejection of claims 1, 2, 4-5, 9-16, 18, 42-50, 52, 54, 56, 58, 59, under 35 U.S.C. 103(a) as being unpatentable over Yamazaki et al. [US 6,699,719] in view of Umek et al. [US 2003/0124572] has been withdrawn.

### ***Claim Rejections - 35 USC § 112***

4. The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

5. Claims 1, 42, 49, 57 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the

Art Unit: 1641

claimed invention. In particular, the specification at the time the application was filed failed to disclose "providing a dried array", or that the arrays of lipid membranes are ever dried.

***Claim Rejections - 35 USC § 102***

6. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

7. Claims 1, 2, 4, 10-16, 18, 52, 57-58, 60, 61 are rejected under 35 U.S.C. 102(e) as being anticipated by Umek et al. [US 2003/0124572].

With respect to claims 1, 57, Umek et al., however, teach immobilized lipid layers that are fixed and/or cross-linked to provide greater stability (para. 0048), wherein the lipid layers are fixed using a coating of amines such as poly-lysine or polyethylene imine (para. 0075) or silanes such as chlorosilanes or alkoxysilanes (para. 0073), wherein the lipids may further comprise membrane components such as cell receptors (para. 0056), thus forming doped lipids which are used to measure the effect of cell affecting agents such as toxins (para. 0089). The arrays can then be dried and stored for over a year (para. 0106).

8. With respect to claim 2, Umek et al. teach immobilizing cell components such as cell receptors (para. 0056) for simultaneous screening of potential drug candidates or toxins (para. 0060).

Art Unit: 1641

9. With respect to claim 4, Umek et al. teach immobilizing carbohydrates (para. 0077).
10. With respect to claims 10, 11, 14, Umek et al. teach labeled binding reagents specific for the analytes (para. 0080, 0093)), such as toxins (para. 0060), which would result in labeled toxins that are then measured (para. 0093).
11. With respect to claim 12, Umek et al. teach measuring changes of the effects of cell affecting agents, such as toxins) or conditions on the cells such as changes in temperature, pH or pressure (para. 0089).
12. With respect to claim 13, Umek et al. teach unlabelled ligands (para. 0076), which may be toxins (para. 0060).
13. With respect to claim 15, Umek et al. teach unlabelled ligands (para. 0076), which may be toxins (para. 0060), which are either synthetic or natural.
14. With respect to claims 16, 18, Umek et al. teach multi-well plates comprising glass (para. 0101).
15. With respect to claims 52, 58, as discussed above, the amines used by Umek et al. may be polyamines such as poly-lysine or polyethylene imine (para. 0075).
16. With respect to claims 60 and 61, as discussed above, the amines used by Umek et al. may be silanes containing such as alkoxysilanes (para. 0073).

### ***Claim Rejections - 35 USC § 103***

17. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person

Art Unit: 1641

having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

18. Claim 5 is rejected under 35 U.S.C. 103(a) as being unpatentable over Umek et al. [US 2003/0124572] in view of Cherksey et al. [US 5,750,103]

With respect to claim 5, Umek et al., however, teach immobilized lipid layers that are fixed and/or cross-linked to provide greater stability (para. 0048), wherein the lipid layers are fixed using a coating of amines such as poly-lysine or polyethylene imine (para. 0075) or silanes such as chlorosilanes or alkoxysilanes (para. 0073), wherein the lipids may further comprise membrane components such as cell receptors (para. 0056), thus forming doped lipids which are used to measure the effect of cell affecting agents such as toxins (para. 0089). The arrays can then be dried and stored for over a year (para. 0106). Umek et al. do not teach that the toxin binding moieties are gangliosides.

Cherksey et al., however, teach the use of CNS surface gangliosides which bind to tetanus toxin (column 7, lines 30-45).

Therefore, it would have been obvious to one of ordinary skill in the art at the time of the invention to have used gangliosides such as CNS surface gangliosides, as suggested by Cherksey et al., in order to be able to detect the presence of specific toxins, such as tetanus toxin.

19. Claim 17 is rejected under 35 U.S.C. 103(a) as being unpatentable over Umek et al. [US 2003/0124572] in view of Pluskal et al. [US 5,004,543].

With respect to claim 17, Umek et al., however, teach immobilized lipid layers that are fixed and/or cross-linked to provide greater stability (para. 0048), wherein the lipid layers are fixed using a coating of amines such as poly-lysine or polyethylene imine (para. 0075) or silanes

Art Unit: 1641

such as chlorosilanes or alkoxysilanes (para. 0073), wherein the lipids may further comprise membrane components such as cell receptors (para. 0056), thus forming doped lipids which are used to measure the effect of cell affecting agents such as toxins (para. 0089). The arrays can then be dried and stored for over a year (para. 0106). Umek et al. do not teach a microporous support.

Pluskal et al., however, teach a charge-modified, hydrophobic microporous membrane and further teaches that the membrane exhibits a combination of ionic and hydrophobic properties, rendering them highly effective for macromolecular adsorption applications under a variety of conditions (column 2, lines 35-46).

Therefore, it would have been obvious to one of ordinary skill in the art to have a charge-modified, hydrophobic microporous membrane as the support in the method of Umek et al., as suggested by Pluskal et al., as the membrane is highly effective for macromolecular adsorption applications under a variety of conditions.

20. Claims 9, 42-50, 54, 56, are rejected under 35 U.S.C. 103(a) as being unpatentable over Umek et al. [US 2003/0124572] in view of Fang et al. [US 2002/0094544].

With respect to claims 9, 42, 49, Umek et al., however, teach immobilized lipid layers that are fixed and/or cross-linked to provide greater stability (para. 0048), wherein the lipid layers are fixed using a coating of amines such as poly-lysine or polyethylene imine (para. 0075) or silanes such as chlorosilanes or alkoxysilanes (para. 0073), wherein the lipids may further comprise membrane components such as cell receptors (para. 0056), thus forming doped lipids which are used to measure the effect of cell affecting agents such as toxins (para. 0089). The

Art Unit: 1641

arrays can then be dried and stored for over a year (para. 0106). Umek et al. do not teach that the lipid membranes are deposited in microspots.

Fang et al., however, teach detection of a binding event involving a probe array comprising a plurality of probe microspots associated with a surface of a substrate (para. 0031). Fang et al. further teach that different microspots may correspond to different probes (para. 0040).

Therefore, it would have been obvious to one of ordinary skill in the art at the time of the invention for the array of Umek et al. to be arranged as an array of distinct microspots, as suggested by Fang et al., in order to allow for different probes to detect the binding of different analytes, thus providing more versatility and flexibility to the arrays of Umek et al.

21. With respect to claims 43, Umek et al. teach labeled binding reagents specific for the analytes (para. 0080, 0093)), such as toxins (para. 0060), which would result in labeled toxins that are then measured (para. 0093)

22. With respect to claim 44, Umek et al. teach that the detection may be luminescence (para. 0007).

23. With respect to claim 45, Umek et al. teach a wash step to remove unbound ligands (para. 0185).

24. With respect to claims 46-48, Umek et al. teach labeled ligands (para. 0045) and unlabelled ligands for blocking (para. 0076) and further teach measuring changes of the effects of cell affecting agents, such as toxins) or conditions on the cells such as changes in temperature, pH or pressure (para. 0089) or measurement of resistance or impedance (para. 0009).



Art Unit: 1641

25. With respect to claim 50, Umek et al. teach detection of toxins (para. 0060), in samples such as tissues (para. 0049).

26. With respect to claims 54, 56, as discussed above, the amines used by Umek et al. may be polyamines such as poly-lysine or polyethylene imine (para. 0075).

27. Claims 51, 59, are rejected under 35 U.S.C. 103(a) as being unpatentable over Umek et al. [US 2003/0124572] in view of Patton [US 4,933,285].

With respect to claims 51, 59, Umek et al. teach immobilized lipid layers that are fixed and/or cross-linked to provide greater stability (para. 0048), wherein the lipid layers are fixed using a coating of amines such as poly-lysine or polyethylene imine (para. 0075) or silanes such as chlorosilanes or alkoxysilanes (para. 0073), wherein the lipids may further comprise membrane components such as cell receptors (para. 0056), thus forming doped lipids which are used to measure the effect of cell affecting agents such as toxins (para. 0089). The arrays can then be dried and stored for over a year (para. 0106). Umek et al. do not teach a coating of  $\gamma$ -aminopropylsilane on the support.

Patton, however, teaches substrates comprising coatings of  $\gamma$ -aminopropylsilane (column 4, lines 15-20). Patton further teaches that this produces solid phases that serve to anchor reaction products to a solid phase, while permitting the unreacted reagents to be removed (column 3, lines 35-42). Therefore, this would allow Umek et al. to anchor lipid membranes to the support that have reacted with the  $\gamma$ -aminopropylsilane, while removing unbound lipid membranes.

Therefore, it would have been obvious to one of ordinary skill in the art at the time of the invention to have a coating of  $\gamma$ -aminopropylsilane to anchor lipid membranes to the support that have reacted with the  $\gamma$ -aminopropylsilane, while removing unbound lipid membranes, thus providing a more stable structure for detecting toxins, allowing for a stronger signal.

28. Claims 53, 55, are rejected under 35 U.S.C. 103(a) as being unpatentable over Umek et al. [US 2003/0124572] in view of Fang et al. [US 2002/0094544], as applied to claims 42 and 49 above, and further in view of Patton [US 4,933,285].

With respect to claims 53, 55, Umek et al. teach immobilized lipid layers that are fixed and/or cross-linked to provide greater stability (para. 0048), wherein the lipid layers are fixed using a coating of amines such as poly-lysine or polyethylene imine (para. 0075) or silanes such as chlorosilanes or alkoxysilanes (para. 0073), wherein the lipids may further comprise membrane components such as cell receptors (para. 0056), thus forming doped lipids which are used to measure the effect of cell affecting agents such as toxins (para. 0089). The arrays can then be dried and stored for over a year (para. 0106). Umek et al. do not teach a coating of  $\gamma$ -aminopropylsilane on the support.

Patton, however, teaches substrates comprising coatings of  $\gamma$ -aminopropylsilane (column 4, lines 15-20). Patton further teaches that this produces solid phases that serve to anchor reaction products to a solid phase, while permitting the unreacted reagents to be removed (column 3, lines 35-42). Therefore, this would allow Umek et al. to anchor lipid membranes to the support that have reacted with the  $\gamma$ -aminopropylsilane, while removing unbound lipid membranes.

Therefore, it would have been obvious to one of ordinary skill in the art at the time of the invention to have a coating of  $\gamma$ -aminopropylsilane to anchor lipid membranes to the support that have reacted with the  $\gamma$ -aminopropylsilane, while removing unbound lipid membranes, thus providing a more stable structure for detecting toxins, allowing for a stronger signal.

### ***Response to Arguments***

29. Applicant's arguments filed March 31, 2008 have been fully considered but they are not persuasive. In particular, with respect to applicant's argument that Umek et al. do not teach doped lipids, the Office notes that Umek et al. teach lipid layers which may include components such as receptors or proteins (para. 0038, 0050), resulting in doped lipid layers. It is noted that since applicant has not defined "doped" in the specification, the term must be given its broadest possible interpretation, which is merely that something is added.

30. Therefore, applicant's arguments with respect to Umek et al. are not found persuasive.

31. However, since new grounds of rejections have been made, the office action has not been made final.

### ***Conclusion***

32. No claims are allowed.

33. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Nelson Yang whose telephone number is (571)272-0826. The examiner can normally be reached on 8:30-5:00.

Art Unit: 1641

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Long V. Le can be reached on (571)272-0823. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

34. Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Nelson Yang/  
Patent Examiner, Art Unit 1641